

DOCKET NO.:239461US0CONT

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF:

TAKASHI NAKANO, et al.

SERIAL NO.: 10/632,959

FILED: AUGUST 4, 2003

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: GROUP ART UNIT: 1626

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: EXAMINER: SHIAO, R. T.

FOR: NOVEL CYSTINE DERIVATIVE AND AGENT FOR SUPPRESSING ACTIVATION
OF INFLAMMATORY FACTORS

RESPONSE TO RESTRICTION AND ELECTION OF SPECIES REQUIREMENT

COMMISSIONER FOR PATENTS
ALEXANDRA, VA 22313

SIR:

In response to the Official Action dated June 1, 2004, Applicants elect, with traverse, Group I, Claims 1-20, in part, drawn to compounds/pharmaceutical compositions of the compound of formula (I), wherein the variables Ar^1 and Ar^2 independently do not represent a heterocycle-containing group thereof; the variables R^1 , R^2 , R^3 and R^4 are defined in claim 1; the variables X, Y, T, V, m, and n are as defined in claim 1. Applicants further elect N,N'-bis(2-hydroxybenzyl)-L-cystine as a Species of Group I. Claims 1-31 read on the elected Species.

REMARKS

The Office has restricted this application as follows under 35 U.S.C. §121:

Group I: Claims 1-20, in part, drawn to compounds/pharmaceutical compositions of the compound of formula (I), wherein the variables Ar^1 and Ar^2 independently do not represent a heterocycle-containing group thereof; the variables R^1 , R^2 , R^3 and R^4 are defined in claim 1; the variables X, Y, T, V, m, and n are as defined in claim 1;

- Group II: Claims 1-20, in part, drawn to compounds/pharmaceutical compositions of the compound formula (I), wherein the variables Ar^1 and Ar^2 independently represent a heterocycle-containing group thereof; the variables R^1 , R^2 , R^3 , and R^4 are as defined in claim 1; the variables X, Y, T, V, m, and n are as defined in claim 1; and
- Group III: Claims 21-31, drawn to a method of use (i.e. treating inflammatory disease).

The Examiner is also requiring an election of a single disclosed compound for the group elected. In addition, if Group III is elected, the Examiner is requiring a further election of a single disclosed Species as follows:

- a) Method of treating acute pain;
- b) Method of treating multiple sclerosis;
- c) Method of treating renal failure and etc.

Applicants elect, with traverse, Group I, Claims 1-20, in part, drawn to compounds/pharmaceutical compositions of the compound of formula (I), wherein the variables Ar^1 and Ar^2 independently do not represent a heterocycle-containing group thereof; the variables R^1 , R^2 , R^3 and R^4 are defined in claim 1; the variables X, Y, T, V, m, and n are as defined in claim 1. Applicants further elect N,N'-bis(2-hydroxybenzyl)-L-cystine as a Species of Group I. Claims 1-31 read on the elected Species.

The Office has characterized the inventions of Group IV and Groups I, II, III, and V as mutually exclusive species in an intermediate-final product relationship. Citing MPEP §806.04(b), third paragraph, the Office states that the intermediate product is useful as an antioxidant or as a bleaching agent. The Office furthermore cites MPEP §806.04(h) in support

of its assertion that the inventions are deemed patentably distinct on the ground that there is nothing on record to show them to be obvious variants. Applicants respectfully traverse the Restriction Requirement on the grounds that there is no evidence of record to conclude that the intermediate products are useful as the Office has suggested. Moreover, Applicants respectfully submit that the burden is on the Office to provide reasons to conclude that the inventions are patentably distinct, and is not on the Applicants to establish that they are not. Accordingly, the Restriction Requirement is believed to be improper, and it should be withdrawn.

The Office has characterized the inventions of Groups I-III. Citing MPEP §806.04 and MPEP §808.01, the Office concludes that the invention of these groups are unrelated. However, the Office has not provided sufficient reasons and/or examples to support this assertion. The Office has merely stated the conclusion. Accordingly, the Office has failed to meet the burden necessary in order to sustain the Restriction Requirement. Accordingly, Applicants respectfully submit that the Restriction Requirement should be withdrawn.

In regard to Groups I-II and Group III, the Office has characterized the relationship between these two groups as product and process of use. Citing MPEP §806.05(h), the Office concludes that the product can be used in a materially different process such as "antifungal agents." However, the Office has not provided sufficient reasons and/or examples to support this conclusion. Further, the Office has failed to show that the proposed process is materially different from the claimed process. Accordingly, Applicants respectfully submit that the Office has failed to meet the burden necessary in order to sustain the Restriction Requirement. Withdrawal of the Restriction Requirement is respectfully requested.

Applicants traverse the Restriction Requirement on the grounds that the Office has not shown that a burden exists in searching all the claims of the present application.

Applicants respectfully traverse the Election of Species Requirement on the grounds that the Office has not provided any reasons, whatsoever, to support the conclusion of patentable distinctness. Rather, the Office has merely stated the conclusion.

Applicants make no statement regarding the patentable distinctness of the species, but note that for restriction to be proper, there must be a patentable difference between the species as claimed. MPEP §808.01(a). The Office has not provided any reasons or examples to support a conclusion that the species are indeed patentably distinct. Accordingly, Applicants respectfully submit that the restriction is improper, and Applicants' election of species is for examination purposes only.

Finally, with respect to the elected species, Applicants respectfully submit that, should the elected species be found allowable, the Office should expand its search to the non-elected species.

Moreover, MPEP §803 states as follows:

If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on its merits, even though it includes claims to distinct or independent inventions.

Applicants submit that a search of all claims would not constitute a serious burden on the Office.

Finally, Applicants remind the Examiner that MPEP §821.04 states:

...if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.

Applicants respectfully submit that should the elected group be found allowable, non-elected process claims should be rejoined.

Applicants respectfully submit that the above-identified application is now in condition for examination on the merits, and early notice of such action is earnestly solicited.

Respectfully submitted,

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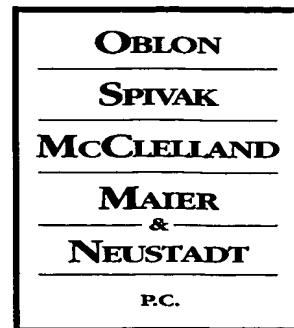
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ALEXANDRIA, VIRGINIA 22313



ATTORNEYS AT LAW

RE: Application Serial No.: 10/632,959
Applicants: Takashi NAKANO, et al.
Filing Date: August 4, 2003
For: NOVEL CYSTINE DERIVATIVE AND AGENT FOR
SUPPRESSING ACTIVATION OF INFLAMMATORY
FACTORS
Group Art Unit: 1626
Examiner: Shiao, R.T.

SIR:

Attached hereto for filing are the following papers:

Response to Restriction and Election of Species Requirement

Our check in the amount of \$0.00 is attached covering any required fees. In the event any variance exists between the amount enclosed and the Patent Office charges for filing the above-noted documents, including any fees required under 37 C.F.R. 1.136 for any necessary Extension of Time to make the filing of the attached documents timely, please charge or credit the difference to our Deposit Account No. 15-0030. Further, if these papers are not considered timely filed, then a petition is hereby made under 37 C.F.R. 1.136 for the necessary extension of time. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

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